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March 11, 2003

The Honorable John Gleeson
United States District Judge
United States District Court
Eastern District of New York
225 Cadman Plaza East
Brooklyn, New York 11201

RE: U.S.A. v. Jason Vale, 02 CR 466

Your Honor:

We are scheduled to argue the Defendant's Motions on March 14, 2003, and write to address two issues. The first concerns the Defendant's Motion to Recuse the Prosecutor. The second concerns the Defendant's Motion for a Bill of Particulars.

Motion for Recusal of Prosecutor

In its reply brief, the government makes a point that we believe is contrary to the applicable law.

The government attorney argues that his role as both an attorney in the civil action and prosecutor in the criminal action presents no conflict. One reason for that, according to the government, is because Mr. Vale's injunction is final and he may not modify it. See United States' Memorandum of Law in Opposition to Defendant Vale's Pre-Trial Motions, n. 5.

We disagree. Mr. Kleinberg's position as both civil and criminal prosecutor of Mr. Vale continues to prejudice Mr. Vale in any efforts to modify the injunction. Under the law it is never too late to modify an injunction proscribing future conduct such as this in certain circumstances.

Federal Rule of Civil Procedure 60(b) contemplates that remedial orders may be modified:

On motion and upon such terms as are just, the court may relieve a party or a party's legal representative from a final judgment, order, or proceeding for the following reasons: ...

- (5) ... it is no longer equitable that the judgment should have prospective application; or
(6) any other reason justifying relief from the operation of the judgment.

See also U.S. v. Secretary of Housing and Urban Development, 239 F.3d 211, 216 (2d Cir. 2001). Furthermore, because consent decrees are injunctions, their modifications are reviewed for abuse of discretion only. Id. (quoting Juan F. v. Weicker, 37 F.3d 874, 878 (2d Cir.1994), cert. denied, 515 U.S. 1142, 115 S.Ct. 2579, 132 L.Ed.2d 829 (1995)).

The text of Federal Rule 60(b) places a one-year time limitation only upon three bases for modification not applicable here. See F.R.C.P. 60(b) ("The motion shall be made within a reasonable time, and for reasons (1), (2), and (3) not more than one year after the judgment, order, or proceeding was entered or taken.").

A change in legal climate is just one example of a circumstance under which this injunction may be modified. See also U.S. v. Eastman Kodak, 63 F.3d 95, 102 (2d Cir. 1995) ("Of course, cases may arise in which modification or termination of a consent decree is appropriate even though the purpose of the decree has not been achieved. For example, there may be significant changes in the factual or legal climate.")

To the extent that the government views the term "promotion" as used in the injunctions as prohibiting Mr. Vale's right to speak freely about his belief in the healing properties of apricot seeds and amygdalin (as opposed to actual sale or distribution), Mr. Vale may wish to seek clarification or modification of the injunctions. While we do not concede that the term "promotion"—a word *not* found in the relevant regulatory statute or regulations on the subject—does reach to free speech, we have no way of knowing until the government puts on its case how they define the term. Do they mean advertising for sale or distribution? Or are they saying that Mr. Vale cannot cite his Bible verses and his personal experiences when talking to others about apricot seeds and amygdalin?

Interestingly, cursory research reveals a series of cases that would appear to undermine any argument that the government would have to restrict Mr. Vale's right to speak freely about his beliefs. We point out the following cases, decided *after* the Permanent Injunction issued in this case.

1. Ashcroft v. Free Speech Coalition, Inc., 122 S.Ct 1389 (2002) – action brought by pornographers to enjoin application of Child Porn Prosecution Act against purveyors of virtual child pornography. Supreme Court held that the potential harms were too attenuated from the proscribed speech and struck the application as overbroad and unconstitutional in violation of

First Amendment. "[T]he Court's First Amendment cases draw vital distinctions between words and deeds, between ideas and conduct . . . The government may not prohibit speech because it increases the chance an unlawful act will be committed 'at some indefinite future time.'" 122 S.Ct 1389, 1403.

2. Conant v. Walters, 309 F.3d 629 (9th Cir. 2002) – in action by physicians seeking to recommend medical marijuana to patients to enjoin federal government from revoking physicians' license or conducting investigations that might lead to such revocation, court upheld portions of injunction finding that the government policy of discouraging open communication between doctor and patient interfered with First Amendment rights.

3. Thompson v. Western States Medical Center, 122 S.Ct 1497 (2002) – in action brought by pharmacies for declaratory relief against FDA Modernization Act, prohibiting advertising and *promotion* of particular compounded drugs, Supreme Court held these provisions were unconstitutional restrictions on commercial speech.

Furthermore, there have been suggestions in the media about ways in which the FDA and the present administration continues to rethink its policies, as well as suggestions that these bodies may be more generous toward people who advocate alternative, particularly religious-based therapies. See, e.g., "Stung By Courts, F.D.A. Rethinks Its Rules," New York Times, October 15, 2002 (copy attached); Dowd, M. "Tribulation Worketh Patience," New York Times, Op-Ed, October 9, 2002 (copy attached).

We quote these cases only to point out possible arguments Mr. Vale might have if he wanted to negotiate with government concerning the terms of the Permanent Injunction, particularly as to the term "promotion." Mr. Kleinberg's position as prosecutor and representative of the FDA, it seems to us, gives him continued advantage in the criminal case and prejudices Mr. Vale in any future actions he may wish to take in the civil case.

Motion for Bill of Particulars

On February 14, 2003, we renewed and modified our request for a Bill of Particulars to address the Superseding Order to Show Cause. The government still refuses to provide the requested particulars.

For the Court's review, the following requests are directed to the Superseding Order to Show Cause. We respectfully incorporate the arguments made in our motion.

1. As to each of Counts One and Two of the Superseding Order to Show Cause, please state the following:

a) the date(s) upon which the government contends that the defendant directly or indirectly introduced or caused to introduce into interstate commerce, held for sale after introduction into interstate commerce, manufactured, processed, packed, labeled, or distributed any product that the government contends is amygdalin, laetrile, Vitamin B-17, and apricot seeds;

b) the person or persons whom the government contends was aiding, abetting, counseling, commanding, inducing, procuring, and causing to perform each of the foregoing acts;

c) the person(s) and/or address(es) to whom the government contends that the defendant introduced or caused to introduce into interstate commerce, held for sale after introduction into interstate commerce, manufactured, processed, packed, labeled, or distributed any product that the government contends is amygdalin, laetrile, Vitamin B-17, and apricot seeds;

d) The phone numbers and web sites that the government contends were contacted that led to the introduction into interstate commerce, holding for sale after introduction into interstate commerce, manufacturing, processing, packing, labeling, or distributing of any product that the government contends is amygdalin, laetrile, Vitamin B-17, and apricot seeds;

e) To the extent that the government claims that the defendant indirectly or directly "caused" products to be introduced into interstate commerce, held for sale after introduction into interstate commerce, manufactured, processed, packed, labeled, or distributed (as opposed to performing any of these actions himself), please state the names and addresses of all persons or entities through whom the government contends any of these actions were performed with respect to amygdalin, laetrile, Vitamin B-17, and apricot seeds, and the dates of the actions.

f) As to each Count, please state the "SAMPLE NUMBER," as referred to in the Memorandum Results of Analysis dated June 5, 2002, that corresponds to any product that the government contends is implicated in that Count;

g) also state from where and when this product, as referred to by SAMPLE NUMBER, was seized or recovered.

2. As to each of Counts Three and Four of the Superseding Order to Show Cause, please state the following:

a) the date(s) upon which the government contends that the defendant promoted, over the internet or otherwise, amygdalin, laetrile, Vitamin B-17, and apricot seeds as a cure, treatment, mitigation, and prevention of cancer;

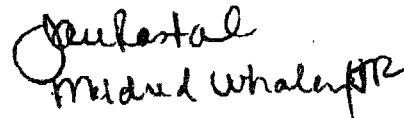
b) the phone numbers, web sites, publications, or any other medium through which the government contends that the defendant promoted, over the internet or otherwise, amygdalin, laetrile, Vitamin B-17, and apricot seeds as a cure, treatment, mitigation, and prevention of cancer

c) the exact words, sentences, phrases and/or images that the government contends constitute promotion over the internet or otherwise, amygdalin, laetrile, Vitamin B-17, and apricot seeds as a cure, treatment, mitigation, and prevention of cancer.

d) the person or persons whom the government contends that the defendant directly and indirectly was aiding, abetting, counseling, commanding, inducing, procuring, and causing to promote.

Thank You for Your attention to this matter.

Respectfully Submitted,

Handwritten signature of Mildred Whalen in cursive, with the name 'Mildred Whalen' clearly legible.

MILDRED WHALEN, ESQ.

JAN ROSTAL, ESQ.

Staff Attorneys

(718) 330-1200

JAR/jar

cc: Charles Klienberg, Esq.

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225 Cadman Plaza East
Brooklyn, New York 11201

RE: U.S.A. v. Jason Vale, 02 CR 466

Your Honor:

We write in response to the government's adjournment letter dated February 20, 2003 ("Kleinberg Letter"). By that letter, the government opposes a bench trial because it would limit Mr. Vale's sentencing exposure to six months.

The Court should be aware of our position, which is that the law supports Your Honor's discretion to hold a bench trial if the maximum exposure is six months in custody. Taylor v. Hayes, 418 U.S. 488 (1974) (defendant not entitled to a jury trial on criminal contempt charges where no more than a six months' sentence had actually been imposed). The Supreme Court has long held that "petty contempt, like other petty criminal offenses may be tried without a jury when the penalty actually imposed does not exceed six months or a longer penalty had not been expressly authorized by statute." Id. at 2701 (citing Bloom v. Illinois, 391 U.S. 194 (1968)).

Therefore, the defense position is that, regardless of the statutory maximum (of which there is none), the Court can indeed trump Mr. Vale's right to a jury trial by limiting the potential sentence to six months.

Nevertheless, the government argues that "a prison term of only six months would be inappropriate in this case." Kleinberg Letter, at 1. We disagree.

We believe a bench trial makes sense. Besides serving the Court's interest in vindicating its authority and the public's interest in prosecuting this case, there are several other justifiable reasons for limiting the sentencing exposure in this case.

I. A Six Month Maximum Penalty Is Not Inconsistent with the Guidelines or the Relevant Statutes

As in any other criminal case, the threshold sentencing question here—should the case get to a sentencing phase—is which guideline applies. The Statutory Index to the Guidelines Manual (Appendix A) directly tracks charges brought under 18 U.S.C. §401 to USSG § 2J1.1 (entitled “Contempt”), which in turn tracks to USSG §2X5.1 (entitled “Other Offenses”). That guideline directs the Court to apply the most analogous offense guideline, or in the absence of such, the provisions of 18 U.S.C. § 3553(b). See United States v. Cefalu, 85 F3d 964 (2d Cir 1996)

The conduct underlying the contempt charged here—that of selling and promoting apricot seeds—is **directly proscribed by statute in 21 U.S.C. §331**. Congress enacted a penalty provision in the Federal Drug and Cosmetic Act (FDCA), 21 U.S.C. §333(a), which states that “any person who violates a provision of section 331 shall be imprisoned for not more than one year or fined not more than \$1000 or both.” The potential penalty increases to three years upon a second conviction or if the offense involves an intent to defraud or mislead. 21 U.S.C. §333(b).

Interestingly, both 21 U.S.C. §331 and §333(a) point to USSG 2N2.1 (entitled “Violations of Statutes and Regulations Dealing With Any Food, Drug, Biological Product, Device, Cosmetic, or Agricultural Product”). The base offense level under USSG 2N2.1 is 6. Assuming that Mr. Vale has no more than one criminal history point, and the discovery suggests he does not, he is in Criminal History Category I, with a corresponding guideline range of 0 to 6 months.

There is a cross-reference in USSG 2N2.1 “if the offense involved fraud” to §2B1.1 (Theft, Property Destruction, and Fraud). Nevertheless, even if the government could prove beyond a reasonable doubt that Mr. Vale violated the injunction, it cannot plausibly argue that Mr. Vale’s conduct amounted to “fraud” in any common sense of the word.

This is not a case in which a seller peddled a product claiming it to be one substance, say aspirin, when it was in fact a sugar pill. People who bought Mr. Vale’s apricot seeds and amygdalin (apricot seed extract) over the years were well informed that they were buying just that—apricot seeds and amygdalin. The crux of the FDA quarrel with Mr. Vale is that the agency disagreed with claims that apricot seeds or amygdalin has any effect on cancer—either Mr. Vale’s or anyone else’s. That does not make out a case of fraud. At most, proof of the allegations in the Order to Show Cause amount to proof of a violation of 21 USC §333(a)—which is a regulatory crime.

We believe that the term “fraud” should not be construed in the abstract way that the government might like in order to apply the higher guidelines of USSG 2B1.1 in this particular case. The Second Circuit, in discussing the landmark Supreme Court decision of McNally v.

